



(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention
of the grant of the patent:
31.03.2004 Bulletin 2004/14

(21) Application number: **99972522.9**

(22) Date of filing: **25.11.1999**

(51) Int Cl.⁷: **A61F 13/02**

(86) International application number:
PCT/DK1999/000658

(87) International publication number:
WO 2000/030580 (02.06.2000 Gazette 2000/22)

(54) **A LAYERED PRODUCT READY FOR NON-TOUCH APPLICATION AND A METHOD FOR
PRODUCING SUCH A PRODUCT**

**SCHICHTPRODUKT ZUR BERÜHRUNGSLOSEN ANWENDUNG UND VERFAHREN ZUR
HERSTELLUNG EINES SOLCHEN PRODUKTES**

**PRODUIT STRATIFIE POUVANT ETRE APPLIQUE SANS CONTACT ET PROCEDE DE
PRODUCTION DUDIT PRODUIT**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**

(30) Priority: **25.11.1998 DK 154798**

(43) Date of publication of application:
04.10.2001 Bulletin 2001/40

(73) Proprietor: **COLOPLAST A/S**
3050 Humlebaek (DK)

(72) Inventors:
• **MARCUSSEN, Jan**
DK-2630 Taastrup (DK)
• **MADSEN, Lars, Bo**
DK-2820 Gentofte (DK)
• **HANSEN, Grazyna**
DK-3520 Farum (DK)

(56) References cited:
WO-A1-97/43991 **WO-A1-98/00080**
US-A- 5 099 832 **US-A- 5 106 629**
US-A- 5 397 297 **US-A- 5 840 052**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a layered product in a package ready for non-touch application which product comprises a cover layer to which an adhesive layer is unreleasably fastened and a release layer which is releasably fastened to the adhesive layer. The package comprises a top layer and a bottom layer where the top layer is next to the cover layer and the bottom layer is next to the adhesive layer and the top and bottom layers are releasably sealed to each other isolating the adhesive layer from the surroundings.

BACKGROUND OF THE INVENTION

[0002] It is desirable to be able to apply an adhesive product such as a dressing without touching the adhesive layer in order to avoid reducing the adhesiveness of the product. Also it is desirable to be able to apply a sterile dressing to a patients skin without touching the surface of the dressing that is to come into contact with the skin in-order to avoid introducing bacteria to the wound.

[0003] The prior art discloses several methods for facilitating handling of wound dressings and one method is described in US patent no. 5.106.629 (NDM Acquisition Corp.). The product of this patent is constituted of three layers: a dimensionally stable backing layer, a transparent adhesive layer and a release layer. When applying the dressing the release layer is removed by using an extending tab attached thereto, to expose the adhesive layer. The remaining layers of the wound dressing are then applied to the wound site with the adhesive layer directly contacting the wound. Once these layers are in place, the dimensionally stable backing member is removed, preferably using an extending tab attached hereto.

[0004] Another method is described in WO 97/43991 (Coloplast A/S). The object of this invention is to ensure easy handling of a wound dressing which dressing comprises a main part and a handle part. The main part comprises a carrier layer, an adhesive layer and a release liner. The handle part comprises one or more tab members designed for use as a "non-touch" grip when applying the dressing to the skin. The tab member and the main part of the dressing do not have all layers in common, as it reduces the force which need to be applied in order to remove the tab members after applying the dressing.

[0005] These two documents explain how to handle the product without touching the adhesive during application but they do not combine discrete packaging of the products with non-touch application of the products.

[0006] A third product - a medical adhesive composite - is described in WO 98/00080 (Minnesota Mining and Manufacturing Company). This medical adhesive com-

posite, e.g. a dressing, is combined with a package, the packaged product comprises a top sheet of packaging material, a carrier material, a conformable backing material, a pressure sensitive adhesive and a bottom sheet of packaging material with a release surface. The carrier material is preferably substantially more rigid than the backing material in order to prevent the backing from wrinkling or folding onto itself in whole or in part during application of the dressing. The carrier material is capable of being attached to the backing by any suitable method, such as heat sealing, adhesives, mechanical bonds, wax coatings etc. The bond is secure, yet releasable, i.e. the carrier and backing can be separated without destroying the integrity of the backing or the bond between the adhesive on the backing and the skin of a patient. In addition the bond between the carrier and the backing should be stronger than the bond between the adhesive on the bottom face of the backing and the release liner or surface of the packaging. Adhering the medical adhesive composites directly to the bottom sheet of the packaging material rather than including a separate release liner on the product simplifies the process of dispensing the medical adhesive composites. The bond strength between the release surface and the bottom sheet is greater than the bond strength between the release surface and the adhesive on the bottom face of the backing.

[0007] This document shows how it is possible to include packaging of the product into a single process but the used process is rather complicated and the packaged product may be difficult to apply.

[0008] In EP patent application No. 938 882 is disclosed a release paper in the form of a sheet with several discrete plasters. The plasters comprise an adhesive layer, covered on one side with the release paper and on the other side with a top film. A pouch covering the wound area may be located between the adhesive and the release paper. The plasters are separated from each others by a perforated line in the release paper. The product is not in the form of a sealed package as it does not comprise a sealing cover layer on top of the construction.

BRIEF DESCRIPTION OF THE INVENTION

[0009] The object of the invention is to provide a product in a discrete package which product is easy to handle without the user touching the adhesive of the product which will be touching the surface to which the product is applied, and at the same time this product is easier and less expensive to produce.

[0010] This object is achieved by fastening the cover layer releasably to the top layer of the package in order to make it possible to use the top layer as a non-touch grip.

[0011] A carrier layer is a coherent web which is used to move the layered product through the production process even after other layers have been cut into their

final size and it reduces the cost of production when the carrier layer is made a part of the finished product instead of wasting the carrier layer totally or partly during the production process.

[0012] In order to make the process very simple the top layer may be the carrier layer but it is also possible to use a second layer as carrier layer and in this case the second layer may be present between the cover layer and the top layer in the finished product. In this case the bond strength R1 between the cover layer and the second layer, is smaller than the bond strength S1 between the second layer and the top layer. In fact S1 may be so large it is considered unreleasably.

[0013] It is possible to add a release layer as a separate layer and use standard material for the process otherwise the release layer can be a release surface on the upper side of the bottom layer of the package.

[0014] In order to make the application procedure as simple as possible for the user of the product it is advantageous that:

- 1) the bond strength R1 between the top layer of the package or a second layer and the cover layer is higher than the bond strength R2 between the adhesive layer and the release layer, and
- 2) the bond strength R4 between the release layer and the bottom layer of the package is higher than the bond strength R2 between the adhesive layer and the release layer, and
- 3) the bond strength between the adhesive layer and the surface to which the product has been applied is higher than the bond strength R1.

[0015] The invention further relates to a method for producing a layered product in a package comprising a top and a bottom layer ready for non-touch application which method comprises the following steps:

- a) providing a web comprising at least three layers: A carrier layer connected to or constituting the top layer of a package, a cover layer and an adhesive layer which two layers are unreleasably fastened to each other,
- b) die cutting the product into discrete portions still attached to the carrier layer,
- c) attaching the bottom layer or a release layer to the adhesive side of the product,
- d) isolating the product by sealing the top layer to the bottom layer about the periphery of the product.

[0016] In one embodiment of the invention the release layer may be attached to the adhesive side of the product before the die cutting of the product.

[0017] When the user apply a dressing which agrees with the above demands for the bond strength between the different layers the user first separates the top layer and the bottom layer of the package. When doing this the release layer - whether this layer is a part of the bot-

tom layer or a separate layer - will come off together with the bottom layer and afterwards the bottom layer and the release layer can be thrown away. This leaves the user with the top layer to which the product comprising the cover layer and an adhesive layer is attached. Now the user can use the top layer of the package to handle the product and assure the product is placed correctly. When the adhesion between the layered product and the surface to which the product is fastened is higher than the bond strength between the top layer and the cover layer the user can remove the top layer of the package from the applicated product without problems and throw it away.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018]

Figure 1 shows a cross-sectional view of a product and a package according to the present invention.

Figure 2 is a schematic diagram of a continuous method of manufacturing a product according to the present invention.

Figure 3 is a schematic diagram of a batchwise method of manufacturing a product according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Figure 1 shows a cross-sectional view of a product and a package. The package is constituted by two outer layers, a top layer 1 and a bottom layer 2. These two layers are sealed together at 3 in a way that completely isolates the product from the surroundings and the sealing represents a bond strength of R3.

A cover layer 4 is placed below the top layer and these two layers are releasably fastened to each other with the bond strength R1. The function of the cover layer 4 is to establish a non-adhesive and comfortable upper side of the product when the product is in use. When the product is a dressing the cover layer can be a woven or non-woven e.g. a polymeric material such as a polyurethane with a certain permeativity for water. It is also possible to place a separate layer (not shown) e.g. a carrier layer between the top layer and the cover layer and then the bond strength S1 between the top layer and the optional carrier layer can suitably be considerably higher than the bond strength R1 between cover layer and the carrier layer.

[0020] Below the cover layer 4 is an adhesive layer 5. The cover layer 4 and the adhesive layer 5 are unreleasably bonded to each other. By unreleasably bonded is understood that it is not possible to separate the two layers and keeping them both intact and according to this definition of "unreleasably" the two layers may consist of one layer with different surface structure on the

upper and lower side. If the product is a dressing the adhesive may contain hydrocolloids.

[0021] The adhesive layer 5 is protected by a release surface. In Figure 1 the release surface is constituted by a separate layer, a release layer 6, but the release surface may also be a part of the surface of the bottom layer having releasing qualities. The bond strength between the adhesive layer 5 and the release surface is R2. The bond strength between an optional separate release layer 6 and the bottom layer 2 is R4.

[0022] Figure 2 shows a schematic diagram of a continuous process which may be used for manufacturing the product of this invention. The primary layered web 9 that enters the process comprises a carrier layer which in this example is the later top layer 1 of the package, a cover layer 4 which will form a non-adhesive - surface of the applied product and a layer of or discrete portions of adhesive 5 which has/have been fastened unreleasably to the cover layer 4.

[0023] A roll 10 contains a supply of release liner and the release liner is attached to the primary layered web 9 at the roll 11. Hereafter the primary web 9 to which the release liner now is attached pass a station 12 where the layers of the web which constitutes the product: The cover layer 4, the adhesive layer 5 and the release layer 6, are cut into desired discrete products. The weed 13 from this action is removed and only the carrier layer - the top layer 1 of the package - still constitutes a coherent layer.

[0024] When the weed 13 has been removed it is time to add the bottom layer of the package to the line of products. A supply roll of the bottom layer is kept at 14 and the bottom layer is attached to the line of products at the station 15.

[0025] After the bottom layer of the package has been attached to the line of products, the individual products has to be isolated. This is done at the station 16 where the top and the bottom layer of the package is fastened releasably to each other by e.g. peel welding.

[0026] It is also possible to apply a more batchwise process for manufacturing of the products. This is especially advantageous if the process producing the web 9 is very fast and it is difficult for a single packaging machine to keep up.

[0027] After the products have passed the roll 12 of figure 2 where the line of products have been die cut, the endless line of products is cut up into units containing several discrete products 22 (in Figure 3 the units contain four discrete products). The units are then collected and moved to a temporary storage or directly to one or more different packing machines. In order to be able to pile the units for storage or transport the units have to be provided with a release liner.

[0028] In Figure 3 is a schematic diagram of a batchwise process where the units consisting of discrete products 22 are arriving to the packing machines in piles 21. The top unit is moved forward and placed on the bottom layer 23 of the package to which layer the re-

lease liner covered surface of the product is fastened with the bond strength R4 by e.g. gluing or peel welding.

[0029] In this process the bottom layer 23 and the top layer 24 of the package is constituted by a single sheet of package material. After placing and fastening the unit on the bottom layer the top layer is folded over the unit and fastened to the bottom layer by the bond strength R3 and to the cover layer of the products by the bond strength R1 e.g. in such a way that the products are isolated as discrete products.

Claims

1. A layered product in a package ready for non-touch application which product comprises a cover layer (4) to which an adhesive layer (5) is unreleasably fastened and a release layer (6) which is releasably fastened to the adhesive layer (5), and which package comprises a top layer (1) and a bottom layer (2) where the top layer (1) is next to the cover layer (4) and the bottom layer (2) is next to the adhesive layer (5) or the release layer (6) and the top and bottom layers (1,2) are releasably sealed to each other isolating the adhesive layer (5) from the surroundings, **characterised in that** the cover layer (4) is releasably fastened to the top layer (1).
2. A layered product in a package ready for non-touch application according to claim 1 wherein a carrier layer forms a part of the packaged product.
3. A layered product in a package ready for non-touch application according to claim 2 wherein the top layer (1) is also the carrier layer.
4. A layered product in a package ready for non-touch application according to claim 2 wherein a second layer forms the carrier layer and the second layer is present between the cover layer (4) and the top layer (1) in the finished product.
5. A layered product in a package ready for non-touch application according to claim 4 wherein the bond strength R1 between the cover layer (4) and the second layer is smaller than the bond strength S1 between the second layer and the top layer (1).
6. A layered product in a package ready for non-touch application according to claim 1-4 wherein a separate release layer (6) is present between the adhesive layer (5) and the bottom layer (2).
7. A layered product in a package ready for non-touch application according to claim 1-5 wherein
 - 1) the bond strength R1 between the top layer (1) of the package or a second layer and the

cover layer (4) is higher than the bond strength R2 between the adhesive layer (5) and the release layer (6), and

2) the bond strength R4 between the release layer (6) and the bottom layer (2) of the package is higher than the bond strength R2 between the adhesive layer (5) and the release layer (6), and

3) the bond strength between the adhesive layer (5) and the surface to which the product has been applied is higher than the bond strength R1.

8. A method for producing a layered product in a package comprising a top and a bottom layer ready for non-touch application which method comprises the following steps:

a) providing a web comprising at least three layers: A carrier layer connected to or constituting the top layer (1) of a package, a cover layer (4) and an adhesive layer (5) which two layers are unreleasably fastened to each other,
b) die cutting the product into discrete portions still attached to the carrier layer,
c) attaching the bottom layer (2) or a release layer (6) to the adhesive side of the product,
d) isolating the product by sealing the top layer (1) to the bottom layer (2) about the periphery of the product.

9. A method for producing a layered product according to claim 8, wherein a release layer (6) is attached to the adhesive side of the product before the die cutting of the product.

Patentansprüche

1. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form, wobei das Produkt eine Deckschicht (4), an der eine Kleberschicht (5) nicht ablösbar befestigt ist, und eine Ablöseschicht (6), die ablösbar an der Kleberschicht (5) befestigt ist, aufweist und die Packung eine obere Schicht (1) und eine untere Schicht (2) besitzt, wobei die obere Schicht (1) zur Deckschicht (4) hin und die untere Schicht (2) zur Kleberschicht (5) oder zur Ablöseschicht (6) hin liegen und die obere Schicht (1) und die untere Schicht (2) trennbar miteinander versiegelt sind und die Kleberschicht (5) von der Umgebung isolieren, **dadurch gekennzeichnet, dass die Deckschicht (4) ablösbar an der oberen Schicht (1) befestigt ist.**
2. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung ge-

brauchsfertiger Form nach Anspruch 1, wobei ein Träger einen Teil des verpackten Produkts bildet.

3. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form nach Anspruch 2, wobei die obere Schicht (1) auch die Trägerschicht ist.
4. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form nach Anspruch 2, wobei eine zweite Schicht die Trägerschicht bildet und die zweite Schicht im fertiggestellten Produkt zwischen der Deckschicht (4) und der oberen Schicht (1) vorliegt.
5. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form, wobei die Verbindungsfestigkeit R 1 zwischen der Deckschicht (4) und der zweiten Schicht kleiner ist als die Verbindungsfestigkeit S 1 zwischen der zweiten Schicht und der oberen Schicht (1).
6. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form nach den Ansprüchen 1 bis 4, wobei eine separate Ablöseschicht (6) zwischen der Kleberschicht (5) und der unteren Schicht (2) vorliegt.
7. Aus Schichten aufgebautes Produkt in einer Packung in zur berührungsfreien Anwendung gebrauchsfertiger Form nach den Ansprüchen 1 bis 5, wobei

1) die Verbindungsfestigkeit R1 zwischen der oberen Schicht (1) der Verpackung oder einer zweiten Schicht und der Deckschicht (4) höher ist als die Verbindungsfestigkeit R2 zwischen der Kleberschicht (5) und der Ablöseschicht (6) und

2) die Verbindungsfestigkeit R4 zwischen der Ablöseschicht (6) und der unteren Schicht (2) der Verpackung größer ist als die Verbindungsfestigkeit R2 zwischen der Kleberschicht (5) und der Ablöseschicht (6) und

3) die Verbindungsfestigkeit zwischen der Kleberschicht (5) und der Oberfläche, auf die das Produkt aufgebracht wurde, höher ist als die Verbindungsfestigkeit R1.

8. Verfahren zur Herstellung eines aus Schichten aufgebauten Produkts in einer Packung, die eine obere Schicht und eine untere Schicht aufweist und in zur berührungsfreien Anwendung gebrauchsfertiger Form vorliegt, wobei das Verfahren folgende Schritte umfasst:

- a) Vorsehen eines Flachmaterials, das mindestens drei Schichten aufweist: eine Trägerschicht, die mit der oberen Schicht (1) verbunden ist oder sie darstellt, eine Deckschicht (4) und eine Kleberschicht (5), wobei diese beiden Schichten nicht ablösbar aneinander befestigt sind,
- b) Stanzen des Produkts in diskrete Abschnitte, die noch mit der Trägerschicht verbunden sind,
- c) Verbinden der unteren Schicht (2) oder einer Ablöseschicht (6) mit der Kleberseite des Produkts,
- d) Isolieren des Produkts durch Versiegeln der oberen Schicht (1) mit der unteren Schicht (2) längs des Umfangs des Produkts.
9. Verfahren zur Herstellung eines aus Schichten aufgebauten Produkts nach Anspruch 8, wobei vor dem Ausstanzen des Produkts eine Ablöseschicht (6) an der Kleberseite des Produkts angebracht wird.
- Revendications**
1. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile, comprenant une couche de revêtement (4) sur laquelle une couche adhésive (5) est fixée de manière à ne pas pouvoir être détachée, et une couche amovible (6) fixée sur la couche adhésive (5) de manière à pouvoir être détachée, et dont le conditionnement comprend une couche supérieure (1) et une couche inférieure (2), ladite couche supérieure (1) étant voisine de la couche de revêtement (4), et ladite couche inférieure (2) voisine de la couche adhésive (5) ou de la couche amovible (6), et lesdites couches supérieure et inférieure (1, 2) étant scellées l'une contre l'autre, de manière à pouvoir être détachées, en isolant la couche adhésive (5) de son environnement, caractérisé en ce que la couche de revêtement (4) est fixée sur la couche supérieure (1) de manière à pouvoir en être détachée.
2. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon la revendication 1, dans lequel une couche de support forme une partie du produit conditionné.
3. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon la revendication 2, dans lequel la couche supérieure (1) est aussi la couche de support.
4. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon la revendication 2, dans lequel une deuxième couche forme la couche de support, et où la deuxième couche est disposée entre la couche de revêtement (4) et la couche supérieure (1) dans le produit fini.
5. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon la revendication 4, où la force d'adhérence R1 entre la couche de revêtement (4) et la deuxième couche est inférieure à la force d'adhérence S1 entre la deuxième couche et la couche supérieure (1).
6. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon les revendications 1 à 4, dans lequel une couche amovible séparée (6) est disposée entre la couche adhésive (5) et la couche inférieure (2).
7. Produit stratifié sous conditionnement prêt pour être appliqué sans contact tactile selon les revendications 1 à 5, dans lequel
- 1) la force d'adhérence R1 entre la couche supérieure (1) du conditionnement ou une deuxième couche et la couche de revêtement (4) est supérieure à la force d'adhérence R2 entre la couche adhésive (5) et la couche amovible (6), et où
- 2) la force d'adhérence R4 entre la couche amovible (6) et la couche inférieure (2) du conditionnement est supérieure à la force d'adhérence R2 entre la couche adhésive (5) et la couche amovible (6), et où
- 3) la force d'adhérence entre la couche adhésive (5) et la surface sur laquelle le produit a été appliqué est supérieure à la force d'adhérence R1.
8. Procédé de production d'un produit stratifié sous conditionnement comprenant une couche supérieure et une couche inférieure, prêt pour être appliqué sans contact tactile, comportant les étapes suivantes :
- a) fourniture d'une toile comprenant trois couches au moins : une couche de support reliée à la couche supérieure (1) d'un conditionnement, ou formant celle-ci, une couche de revêtement (4) et une couche adhésive (5), ces deux couches étant fixées l'une contre l'autre de manière à ne pouvoir être détachées,
- b) découpage à l'emporte-pièce du produit en parties distinctes restant attachées à la couche de support,
- c) fixation de la couche inférieure (2) ou d'une couche amovible (6) sur la face adhésive du produit,
- d) isolement du produit par scellage de la couche supérieure (1) contre la couche inférieure (2) sur la périphérie du produit.

9. Procédé de production d'un produit stratifié selon la revendication 8, dans lequel une couche amovible (6) est fixée sur la face adhésive du produit avant le découpage à l'emporte-pièce du produit.

5

10

15

20

25

30

35

40

45

50

55

7

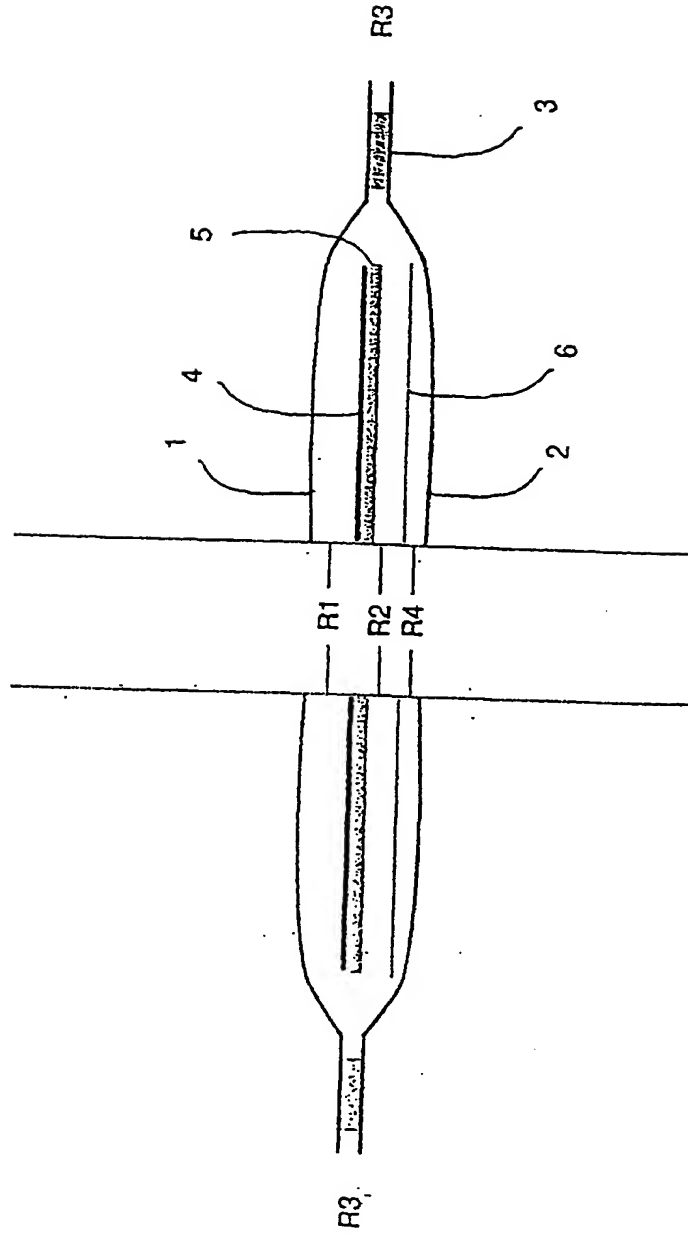


Fig. 1

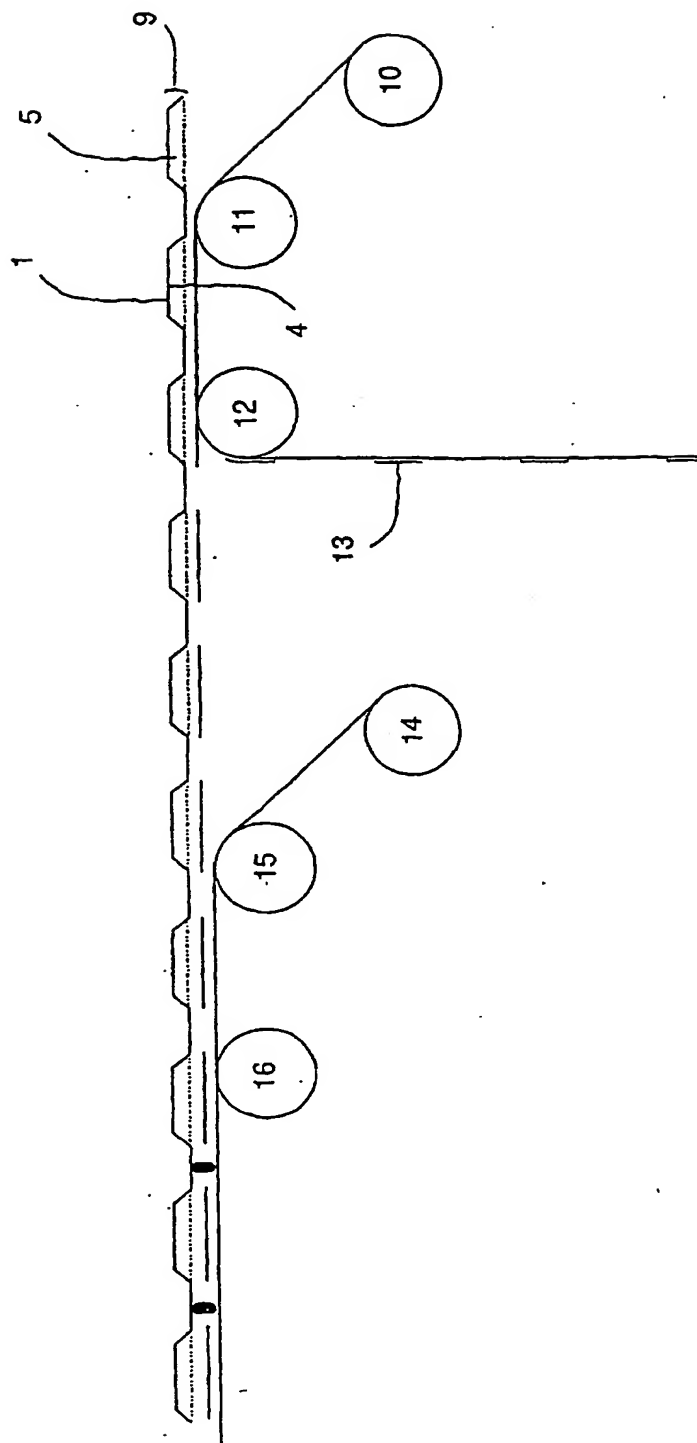


Fig. 2

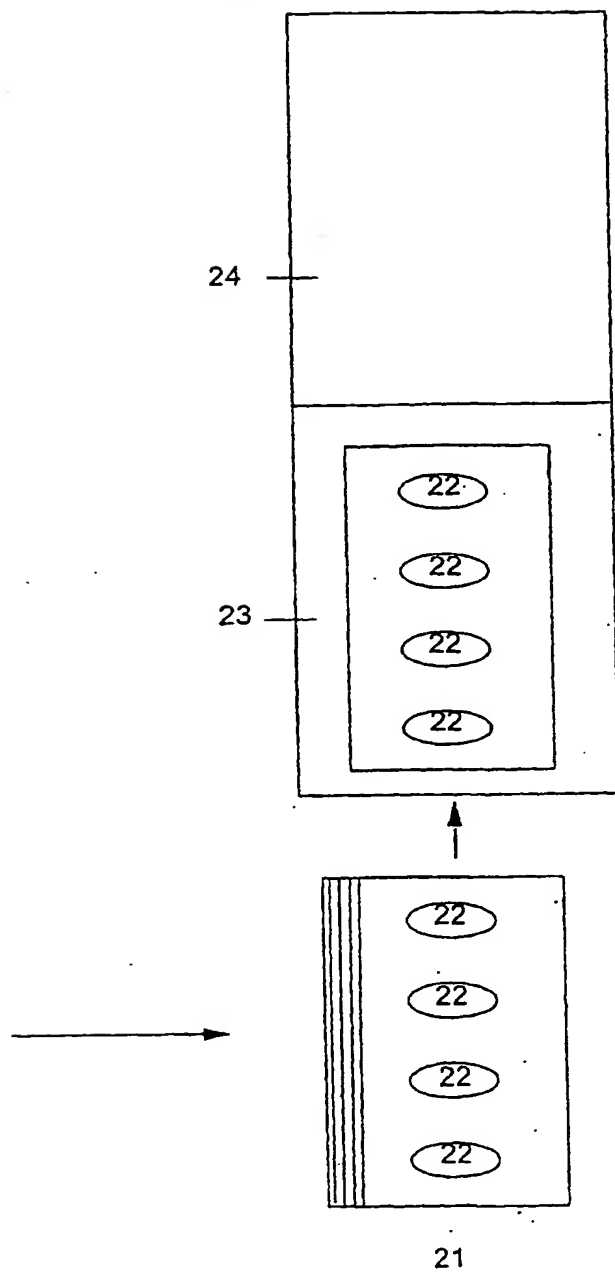


Fig. 3